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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,919	03/15/2001	Hiroshi Sano	026350-048	2905

7590 02/27/2003
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EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 02/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/805,919

Applicant(s)

SANO ET AL.

Examin r

Cynthia Collins

Art Unit

1638

-- The MAILING DATE of this communication app ars on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 03 December 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 7-22 is/are pending in the application.
- 4a) Of the above claim(s) 1,2 and 7-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

The Amendment filed December 3, 2002, paper no.11, has been entered.

Claims 3-6 are cancelled.

Claims 19-22 are newly added.

Claims 1-2 and 7-22 are pending.

Claims 1-2 and 7-18 are withdrawn from consideration as being directed to nonelected inventions.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Specification

The amendment of the abstract was not entered because a marked-up version of the amended abstract was not submitted.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated DNA molecule comprising a nucleotide sequence of SEQ ID NO:2 or a nucleotide sequence encoding the amino acid sequence of SEQ ID NO:1, wherein the

nucleotide sequence encodes a transmembrane protein, wherein the expression of said nucleotide sequence is induced by induced by injury stress, osmotic stress, salt stress and low-temperature stress, and wherein the expression of said nucleotide sequence renders a plant transformed therewith resistant to osmotic stress, does not reasonably provide enablement for isolated DNA molecules comprising nucleotide sequences whose expression is induced by any environmental stress and whose expression renders a plant transformed therewith resistant to any type of environmental stress, or for isolated DNA molecules comprising nucleotide sequences obtained by nucleotide replacement, deletion or insertion in the nucleotide sequence of SEQ ID NO:2 or a nucleotide sequence encoding SEQ ID NO:1, or for isolated DNA molecules encoding an enzymatically active polypeptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification discloses the isolation of a full-length cDNA molecule from tobacco (SEQ ID NO:2) that encodes a polypeptide (SEQ ID NO:1) that is localized on the plasma membrane, and that has homology to receptor-like kinase transmembrane proteins (pages 16-17). The polypeptide of SEQ ID NO:1 is composed of a hydrophobic signal sequence, a helix transmembrane region, and a hydrophilic C-terminus, but SEQ ID NO:1 lacks the kinase domain characteristic of receptor-like kinase proteins, indicating that SEQ ID NO:1 may be a type I transmembrane protein (pages 16-17). The specification also discloses that SEQ ID NO:2 hybridizes to an RNA transcript that is induced by injury stress, osmotic stress, salt stress and low-temperature stress, but not dehydration stress (pages 17-18). Additionally, the specification discloses that the polypeptide of SEQ ID NO:1 may function in plants as a stress sensor, and that

expression of SEQ ID NO:2 in a transgenic plant may confer tolerance to injury stress, osmotic stress, salt stress and low-temperature stress (page 2). Finally, the reference of Tamura et al., submitted with Applicant's response, discloses that expression of SEQ ID NO:2 in transgenic tobacco plants confers tolerance to osmotic stress, but not to salt stress, as compared to nontransformed control plants.

First, the expression of a gene may be induced by one type environmental stress but not another. For example, the instant specification reveals that injury stress, osmotic stress, salt stress and low-temperature stress induce the expression of the gene corresponding to the claimed nucleotide sequences, but dehydration stress does not (page 18). In light of the unpredictability of environmental stress on the induction of gene expression, the specification does not provide sufficient guidance for one skilled in the art to determine, without undue experimentation, how to induce the expression of the native gene corresponding to SEQ ID NO:1 using any type of environmental stress.

Second, the expression of a nucleotide sequence in a transgenic plant may or may not render the plant resistant to the type of stress that induces the expression of the native gene. For example, the submitted reference of Tamura et al. reveals that expression of SEQ ID NO:2 in transgenic tobacco plants renders the plants resistant to osmotic stress, but not to salt stress. In light of the unpredictability of the effect of expressing a nucleotide sequence on environmental stress resistance in transgenic plants, the specification does not provide sufficient guidance for one skilled in the art to determine, without undue experimentation, how to express SEQ ID NO:1 such that a transgenic plant is rendered resistance to all types of environmental stress.

Third, it is well known in the art that the replacement, deletion or insertion of a nucleotide in a nucleotide sequence encoding a polypeptide may or may not alter or eliminate the specific function of that polypeptide, depending on where the replacement, deletion or insertion is made. However, the instant specification does not indicate what regions of SEQ ID NO:1 are critical to the function of the polypeptide it represents and which regions are not. In light of the unpredictability of the effect of replacing, deleting or inserting a nucleotide in the nucleotide sequence of SEQ ID NO:2 or a nucleotide sequence encoding SEQ ID NO:1, the specification does not provide sufficient guidance for one skilled in the art to determine, without undue experimentation, how to replace, delete or insert a nucleotide in the nucleotide sequence of SEQ ID NO:2 or a nucleotide sequence encoding SEQ ID NO:1 such that the function of SEQ ID NO:1 is not altered or eliminated.

Fourth, a polypeptide encoded by an isolated DNA molecule may exert its effect in a transgenic plant enzymatically or non-enzymatically, depending on the specific structural and functional characteristics of the polypeptide. In the instant case, the specification suggests that the polypeptide of SEQ ID NO:1 may exert its effect non-enzymatically, as SEQ ID NO:1 lacks a kinase domain, and is thought to function through self-dimerization and interaction with other protein molecules (page 17). The specification does not provide sufficient guidance for one skilled in the art to determine, without undue experimentation, what enzymatic activity, if any, is exhibited by the polypeptide of SEQ ID NO:1.

Claims 19-21, and claim 22 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is indefinite in the recitation of “environmental stress”. It is unclear what type of environmental stress is intended, as any biotic or abiotic component of the environment may be a source of stress to a plant, such as insects, pathogens, wind, salt, drought, temperature, etc.

Claim 19 is indefinite in the recitation of “wherein said amino acid sequence is induced” and “wherein an amino acid sequence encoded by the modified nucleotide sequence is induced”, as it is unclear in what way an amino acid sequence would be “induced”. It is suggested that the claims be amended to reflect that the transcription or expression of the nucleotide sequence encoding the amino acid sequence is induced by an environmental stress.

Claim 20 is indefinite in the recitation of “encoding the amino acid sequence according to claim 19”, as claim 19 is directed to an isolated DNA molecule.

Claim 21 is indefinite in the recitation of “encoding an enzymatically active polypeptide as claimed in claim 19”. First, claim 19 is directed to an isolated DNA molecule. Second, it is unclear what type of enzymatic activity is exhibited by the polypeptide, as a polypeptide may exhibit one or more specific enzymatic activities.

Claim 21 is indefinite in the recitation of "can hybridize under stringent conditions", for the reasons of record set forth for claim 5 in the office action mailed July 3, 2002.

Applicant's arguments filed December 3, 2002, have been fully considered but they are not persuasive.

Applicant argues that the language regarding stringent hybridization conditions is not indefinite, because the specification discloses at least one hybridization technique that can be used, and because hybridization techniques are well known in the art (reply page 6).

The Office maintains that the language regarding stringent hybridization conditions is indefinite because the claim is not limited to the disclosed hybridization conditions, and because those skilled in the art define "stringent conditions" differently.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19 and 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (Proc. Natl. Acad. Sci. USA, May 1999, Vol. 96, pages 5873-5877).

The claims are drawn to an isolated DNA molecule comprising either (a) a nucleotide sequence encoding an amino acid sequence of SEQ ID NO:1 wherein said amino acid sequence is induced by environmental stress and renders a transgenic plant resistant to environmental stress, or (b) a modified nucleotide sequence obtained by nucleotide replacement, deletion or

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insertion in the nucleotide sequence of (a) wherein an amino acid sequence encoded by the modified nucleotide sequence is induced by and renders a transgenic plant resistant to environmental stress, including a DNA molecule according to claim 19 wherein said environmental stress is injury stress, osmotic pressure stress, salt stress or low-temperature stress, and an isolated DNA molecule encoding an enzymatically active polypeptide as claimed in claim 19 wherein said nucleotide sequence (a) and said modified sequence (b) can hybridize under stringent conditions.

Lee et al. teach an isolated DNA molecule whose expression is induced by environmental stress, including osmotic pressure stress, salt stress and low-temperature stress, and whose expression renders transgenic plant cells resistant to environmental stress, including osmotic pressure stress, salt stress and low-temperature stress (page 5874 Figure 1; page 5875 Figure 3; page 5876 Figure 4). Although the isolated DNA molecule taught by Lee et al. does not encode an amino acid sequence of SEQ ID NO:1, the isolated DNA molecule taught by Lee et al. is a modified nucleotide sequence obtained by nucleotide replacement, deletion or insertion in the nucleotide sequence of (a) because the claim places no limitations on which or how many nucleotides are replaced, deleted or inserted in the nucleotide sequence of (a). Furthermore, the isolated DNA molecule taught by Lee et al. would necessarily hybridize with the nucleotide sequence of (a) under stringent hybridization conditions because the claim places no specific limitations on the hybridization conditions that may be used.

Allowable Subject Matter

Claim 20 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form.

Remarks

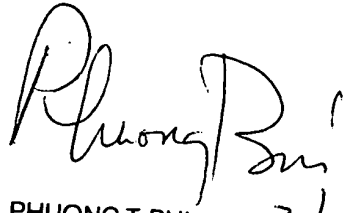
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
February 24, 2003


PHUONG T. BUI
PRIMARY EXAMINER 2/24/03